The elected claims are Claims 17-24. The only rejection of these claims still adhered to by the Examiner is under 35 U.S.C. §103(a) as being unpatentable over the European patent No. 204,596, the rejection over the Canadian patent having been withdrawn by him.

The invention relates to an oral or dermal medicinal composition containing a pharmaceutical active substance and a thermoplastic coating and binding agent prepared by a method of applying a thermoplastic coating and binding agent in a hot-melt liquid state to said oral or dermal medicinal composition, followed by cooling to solidify the thermoplastic coating and binding agent, wherein said thermoplastic coating and binding agent consists essentially of a non-homogenous mixture of, based on 100% by weight of A and B:

A) 5-95% of a thermoplastic acrylic plastic with a melting temperature above room temperature and below 200°C, a glass transition temperature below 120°C, and a melt viscosity pf 1,000 to 1,000,000 Pa-sec at the melting temperature; and

B) 95-5% of a flow improver, which, at room temperature, is not compatible with the thermoplastic acrylic plastic, has a melting temperature above room temperature but below 200°C, a weight average molecular weight under 20,000 d, and a melt viscosity below 100 Pa·sec at the melting temperature of the acrylic plastic.

It is the Examiner's position that the European patent, particularly in its Example 17, discloses a composition which assertedly would inherently exhibit the claimed non-homogeneity upon solidification.

It is again submitted that this is not a viable position.

The defined incompatibility, i.e., non-homogenous mixture, has the effect that in the solidified melt, components A and B are present as separate phases, and flow improver B is

not present dissolved in polymer phase A as a plasticizer. Such clearly is contrary to the objective of the reference.

Specifically, in the European patent the excipients are selected in such a way that they exert a dissolving or gelling effect and a lubricating effect on the polymer. By using such excipients a homogeneous mixture is formed which is compatible even after solidification due to the dissolving or gelling effect of the excipients. A solidified composition obtained from the melt thus remains soft and sticky on its surface, not being suitable as a medicinal form surface. This is not the case in the claimed invention where the defined components A and B are so selected that their combination provides for an incompatible, nonhomogeneous mixture upon solidification. This clearly is against the express requirement of the reference.

Specifically, when a nonhomogeneous mixture would be obtained by using an excipient selected from the classes of materials disclosed by the European patent, such excipient would not be useful for attaining patentee's objective. Note that homogeneity depends not only on the requisite selection of a particular excipient, but also in combining such selected excipient with a particular polymer. Thus, while in Example 17 of the European patent referred to by the Examiner a polymer within the scope of the claims is present, nevertheless, only a specific excipient is illustrated as being combinable therewith, such specific excipient, however, providing for a homogeneous mixture wherein the excipient has a plasticizing effect to dissolve or gel the polymer which does not segregate upon cooling due to the dissolving or gelling effect. In the claimed invention, on the other hand, contrariwise, the selected combination must be such so as to obtain an incompatible, nonhomogenous mixture of the components upon cooling. Such selection clearly is

contraindicated and not inherent in the European patent, it manifestly teaching away therefrom.

Accordingly, withdrawal of the rejection of the claims under 35 U.S.C. §103 over the European patent is requested.

It is submitted that the claims define a patentable invention. Their allowance is solicited.

Respectfully submitted,

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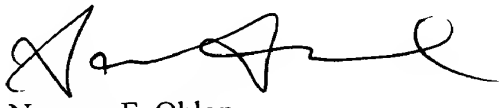

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